Document 64

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### I. INTRODUCTION

Plaintiffs The Laryngeal Mask Company Ltd. and LMA North America, Inc. (collectively, "LMA") respectfully oppose the motion of Defendants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd. (collectively, "Ambu") for leave to amend their answer and add false-advertising counterclaims. Ambu sent LMA a cease-and-desist letter complaining of LMA's sales and marketing practices more than three-and-a-half years ago, but it failed to assert false-advertising claims at that time or when it answered LMA's patent-infringement complaint more than seven months ago.

The only explanation for Ambu's effort to assert false-advertising counterclaims now rather than when it first answered and filed patent-related counterclaims is to delay resolution of LMA's patent-infringement claim and prejudice LMA. The parties have already developed a discovery plan, obtained a case-management schedule, and started the document-gathering and production process based on the present patent-related claims and counterclaims.

For its part, Ambu would suffer no prejudice from denial of its motion. Ambu's false-advertising counterclaims are permissive and may be brought by Ambu in a separate action. Indeed, Ambu's false-advertising counterclaims are wholly unrelated to LMA's patent infringement claim and involve a completely different product feature (the airway tube) than LMA's patent claims (which involve the reinforced tip). Adding Ambu's false-advertising counterclaims to this patent case would not serve judicial economy and would instead complicate this case and tend to confuse the jury.

Accordingly, Ambu's motion to add unrelated false-advertising counterclaims to this patent case should be denied.

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<sup>1</sup> LMA's Opposition is supported by the Declarations of Stephen Marzen and John Sganga filed herewith and the Exhibits 1 through 7 attached thereto.

### II. FACTUAL BACKGROUND

### A. Ambu's Cease-and-Desist Demand in Fall 2004

On November 15, 2004, counsel for Defendant Ambu Inc. wrote to the then-president of LMA NA and demanded that LMA NA "cease and desist" from distributing any materials stating that Ambu's laryngeal mask "causes nerve damage." Letter from Paul Grandinetti to Steve C. Mendell (Nov. 15, 2004), at 1, Declaration of Stephen Marzen, Ex. 5.

On November 19, 2004, counsel for Defendant LMA NA responded that "helical computed tomography scans of cadavers" showed that Ambu's laryngeal mask "can press the Hyoid bone in the same area as the hypoglossal nerve" and "[t]hat pressure could lead to nerve damage." Letter from Stephen Marzen to Paul Grandinetti (Nov. 19, 2004), at 1, Marzen Decl., Ex. 6. Not only did LMA NA ignore Ambu Inc.'s demand to cease and desist, but it also accused Ambu Inc. of passing off the Ambu laryngeal mask as a genuine LMA®-brand laryngeal mask and trading on the reputation and goodwill of the inventor, Dr. Archie Brain. *Id.* at 1-2. LMA NA demanded that Ambu Inc. "stop marketing its supraglottic airway device as an LMA® and as a device developed in collaboration with Dr. Brain" and insisted that Ambu Inc. "respect LMA's intellectual property, including its patents and trademarks." *Id.* at 2.

On December 22, 2004, counsel for Ambu Inc. replied that "Ambu has warned its sales staff against making any such statements" and that it "expects LMA to honor Ambu's demand that LMA cease alleging that the Ambu® Laryngeal Mask 'causes nerve damage' and cease distributing literature stating that Ambu's product 'possibly' increases the 'chance' of hypoglossal or lingual never damage." Letter from Paul Grandinetti to Stephen Marzen (Dec. 22, 2004), at 1-2, Marzen Decl. Ex. 7. Ambu Inc.'s counsel closed by asserting that "Ambu expects the management of LMA to behave responsibly and considers this matter closed." *Id.* at

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## B. LMA's Commencement of This Action Nine Months Ago and Ambu's Insistence on Answering Immediately Despite LMA's Then-Pending Disqualification Motion

LMA commenced this patent-infringement action on October 15, 2007. Dkt. #1. On Friday, October 26, 2007, Ambu's first counsel, Finnegan Henderson Farabow Garrett & Dunner, LLP ("Finnegan"), called to announce that it would represent Ambu and would like an extension of time to answer or otherwise respond to the complaint. Because LMA had previously provided confidential information to Finnegan and obtained legal advice from Finnegan in this same case, LMA's counsel objected to Finnegan's representation the next business day, on Monday, October 29, 2007, and requested that Finnegan withdraw as Ambu's counsel. Ambu and Finnegan rejected LMA's request, however, and on November 29 and December 3, 2007, Finnegan formally appeared in this lawsuit for Ambu through attorney *pro hac vice* applications. Dkt. ##11-14.

To minimize further dissemination of LMA's confidential information shared with Finnegan, LMA asked Finnegan not to work on the case pending the Court's resolution of the disqualification issue. To that end, LMA volunteered Ambu further extensions of time to answer the Complaint. Ambu ignored LMA's request and offers of additional extensions of time to answer. On December 5, 2007, Ambu Inc. filed an answer and two counterclaims alleging invalidity and non-infringement of LMA's patents. Dkt. #15. The next day, December 6, 2007, LMA moved to disqualify Finnegan. Dkt. #16. On January 30, 2008, the other three Ambu defendants filed answers and counterclaims identical to those filed by Ambu Inc. Dkt. #39.

### C. The Court's Disqualification Order and Commencement of Discovery

On February 25, 2008, this Court disqualified Finnegan (Dkt. #41). Ambu's new counsel appeared on March 17, 2008 (Dkt. #43) and requested and obtained an extension of time for the Early Neutral Evaluation Conference, which was finally conducted on June 10, 2008. On June 12, 2008, Magistrate Judge Stormes entered a Scheduling Order regulating discovery and setting a trial date of December 7, 2009. Dkt. #58. Pursuant to the Scheduling Order, the parties began the discovery process, with LMA producing documents relating to its patent claims on June 24,

2008. Throughout this period of time, Ambu had not raised the issue or suggested the possibility of adding any new unrelated counterclaims to the case.

### D. Ambu's Belated Proposal to Add Stale False-Advertising Counterclaims

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More than three-and-a-half years after sending its cease-and-desist letter, on July 3, 2008, Ambu informed LMA that it intended to add false-advertising counterclaims. Those claims rest primarily on the allegation that "LMA falsely claims in its advertising and other marketing materials that Ambu's laryngeal mask airway products cause nerve damage to patients." Memorandum of Points and Authorities in Support of Ambu's Motion for Leave to Amend Answer and Counterclaims ("Ambu Mem.") Ex. A ¶¶ 15-20.²

On July 11, 2008, Ambu filed this motion for leave to amend its answer and add counterclaims. The motion seeks leave to add one new federal and four new state counterclaims – namely, (1) false advertising in violation of § 43(a) of the Lanham Act; (2) false advertising in violation of Cal. Bus. & Prof. Code § 17500, et seq.; (3) trade libel in violation of Cal. Civ. Code § 45; (4) international interference with prospective economic relations; and (5) unfair competition pursuant to Cal. Bus. & Prof. Code § 17200 et. seq. Those claims rest on Ambu's allegations (i) that LMA made false statements in a marketing brochure (to which Ambu refers as the "LMA Brochure") that Ambu products "cause" nerve damage based on a study performed by Dr. David Z. Ferson, and (ii) that LMA falsely represented that customers have switched from Ambu to LMA as a result of safety concerns. See Ambu Mem. at 2-3, and Ex. A ¶ 15. The "literature" that Ambu calls the LMA Brochure and the Ferson Study is attached to the Marzen Declaration as Ex. 4.

Ambu's false-advertising claims are not related to LMA's patent-infringement claims. LMA's patent-infringement claims relate to Ambu's use of a "reinforced tip," which Ambu's product literature admits "will not bend during insertion." Sganga Decl. Ex. 2. The LMA patent

Sganga ("Sganga Decl.") Ex. 1 (Sganga-Morrow email string)

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<sup>&</sup>lt;sup>2</sup> Contrary to Ambu's assertion (Motion at 5; Ex. A (C. Morrow Decl.)), LMA did not "refuse" Ambu's request for a stipulation to file the proposed counterclaims and instead requested a copy of the proposed amended pleading, which Ambu failed to provide. See Declaration of John

in suit likewise describes preventing the device from "folding over on itself during the insertion procedure" by "stiffen[ing] the leading end of the LMA-device . . ." Sganga Decl. Ex. 3, '100 Patent at 1:48-55. By contrast, Ambu's false-advertising counterclaims regarding "nerve damage" relate not to the reinforced tip of the Ambu device, but rather to the "pre-curved shape and the rigidity of its tube." Declaration of Stephen Marzen ("Marzen Decl.") Ex. 4 (quoting from "the LMA Brochure" or "Ferson Study"). The shape or rigidity of the airway tube is not at issue in LMA's patent infringement case, and in fact LMA has accused Ambu products of infringing the '100 patent that do not have pre-curved or rigid airway tubes.

In support of its motion, Ambu submits a declaration from Henrik Wendler, an Executive Vice President of Ambu. *See* Ambu's Mem. Exhibit A ("Wendler Decl."). In his declaration, Mr. Wendler concedes that he learned about LMA's allegedly false statements relating to the Ferson Study "[s]everal years ago." *Id.* ¶ 3. He further asserts that LMA's advertising to Ambu's customers that certain institutions have switched from Ambu to LMA based on safety reasons "beg[an] several years ago." *Id.* ¶ 2. In addition, Mr. Wendler claims that "Ambu was under the impression that LMA had ceased the above marketing and sales tactics," but that Ambu very recently learned, on or about July 1, 2008, that LMA has resumed the conduct described above." *Id.* ¶ 6. Mr. Wendler, however, provides no reason why Ambu would have been under that impression. Nor does Mr. Wendler or Ambu reveal that, when Ambu demanded in the fall of 2004 that LMA cease and desist the marketing practices at issue, LMA specifically reaffirmed those practices. Marzen Decl., Exs. 5 and 6. Ambu neither insisted on assurances that LMA had discontinued those practices, nor initiated litigation, but instead simply retreated by stating it considered the matter "closed." Marzen Decl. Ex. 7.

# III. AMBU'S BELATED REQUEST TO ADD FIVE NEW UNRELATED COUNTERCLAIMS TO THIS SINGLE PATENT ÎNFRINGEMENT ACTION SHOULD BE DENIED

Rule 13(f) of the Federal Rules of Civil Procedure governs the situation where, as here, a party omits a counterclaim and later seeks leave to assert the tardy counterclaim. Rule 13(f) provides as follows:

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(f) Omitted Counterclaim. The court may permit a party to amend a pleading to add a counterclaim if it was omitted through oversight, inadvertence, or excusable neglect or if justice so requires.

FED. R. CIV. P. 13(f).

Although leave to amend should be granted "if justice so requires," "leave to amend is by no means automatic" Gucci America Inc. v. Exclusive Imports Int'l, No. 99 Civ.11490 (RCC) (FM), 2001 WL 21253, at \*5 (S.D.N.Y. Jan. 9, 2001) (citations omitted). The decision whether to permit an untimely counterclaim lies within the discretion of the district court. See Ralston-Purina Co. v. Bertie, 541 F.2d 1363, 1367 (9th Cir. 1976). "[A] district court need not grant leave to amend where the amendment: (1) prejudices the opposing party; (2) is sought in bad faith; (3) produces an undue delay in litigation; or (4) is futile. Amerisource Bergen Corp. v. Dialysist West, Inc., 465 F.3d 946, 951 (9th Cir. 2006); Lockheed Martin Corp. v. Network Solutions, Inc., 194 F.3d 980, 986 (9th Cir. 1999). As demonstrated below, all of those factors support denial of Ambu's motion.

### Ambu Engaged In Undue Delay

It has been more than nine months since LMA began this patent-infringement action and more than seven months since Ambu filed its answer to LMA's complaint. Ambu admits that it became aware of LMA's alleged misconduct "[s]everal years ago." See Wendler Decl. ¶ 6. Indeed, on November 15, 2004 – more than three and a half years ago – Ambu sent a letter to LMA complaining about LMA's statements regarding the Ferson Study and demanding that LMA "immediately cease and desist from rendering any comments or distributing any materials associating the Ambu Laryngeal Mask with hypoglossal or lingual nerve damage." See Marzen Decl., Ex. 5. Thus, it is undisputed that Ambu has known of the marketing practices it now seeks to challenge for years.

Ambu offers two excuses for its delay in asserting its counterclaims challenging LMA's sale and marketing practices. Neither has merit.

First. Ambu suggests that its motion should be granted simply because the motion "is made before the deadline for amendments set in the court's Scheduling Order." Mem. 2. But the Scheduling Order merely set the deadline for filing motions seeking leave to amend the

pleadings. It did not automatically grant such leave. As the Ninth Circuit explained, in assessing timeliness of a motion to amend a pleading, courts should not "merely ask whether a motion was filed within the period of time allotted by the district court in a Rule 16 scheduling order." *AmerisourceBergen Corp.*, 465 F.3d at 953 (citation omitted). Instead, courts should ask 'whether the moving party knew or should have known the facts and theories raised by the amendment in the original pleading." *Id.* (citation omitted). Thus, the fact that Ambu filed its motion within the time limit set in the Scheduling Order means only that Ambu's motion seeking leave to amend is timely. It does not eliminate Ambu's burden to demonstrate that leave is warranted. Ambu attempts (and fails) to satisfy that burden by its second argument.

Second, Ambu contends that it should be excused from its failure to assert its counterclaims earlier because it recently learned of new facts that support those counterclaims. See Mem. 5 ("Ambu only recently learned that LMA has not abated its illegal sales and marketing tactics"). Ambu's contention is insufficient as a matter of law and fact.

To begin with, as a matter of law, regardless of whether Ambu recently learned of new facts to support its counterclaims, it already had sufficient facts in its possession to assert those counterclaims in one of its earlier pleadings. It is well settled that "[a] party that contends it learned 'new' facts to support a claim should not assert a claim that it could have pleaded in previous pleadings." *Edwards Lifesciences LLC v. Cook Inc.*, No. C 03-03817 JSW, 2008 WL 913328, at \*3 (N.D. Cal. Apr. 2, 2008). Thus, in *Edwards Lifesciences*, the court denied a defendant leave to assert a counterclaim for invalidity based on inequitable conduct on the basis of "new facts" where "the majority of the facts for the inequitable conduct claim were known to Gore even before its previous answer." *Id.* at \*2.

Similarly, in *Switchmusic.com, Inc v. U.S. Music Corp.*, No. CV 04-4588RGKPLAX., 2005 WL 3750748 (C.D. Cal. Dec. 12, 2005), the court rejected defendants' attempt to justify their delay in asserting counterclaims for infringement on the ground that they had recently "learned of 'new' facts involving Plaintiff's alleged infringing activities." *Id.* at \*3. In denying leave to add the counterclaims, the court explained that "[t]he new facts that Defendants allege in the proposed amended Answer and Counterclaims involve guitar models that Plaintiff has

advertised and marketed for more than two years prior to the commencement of this case" and that "Defendants have not shown that these facts were unavailable at the time they filed their original Answer and Counterclaims." *Id.* at \*4. Likewise, because Ambu has known about LMA's challenged practices for years, it could and should have asserted its proposed counterclaims in one of its earlier pleadings.<sup>3</sup>

Even if "new facts" could support Ambu's belated counterclaims, Ambu has in fact failed to submit any competent evidence to prove its claim that "Ambu only recently learned that LMA has not abated its illegal sales and marketing tactics." Mem. 5. Ambu's only "evidence" is the declaration of Henrik Wendler, an Ambu Executive Vice President, who asserts that "Ambu" was "under the impression that LMA had ceased the above marketing and sales tactics" and that it was not "until recently, on or about July 1, 2008," that "Ambu" learned that "LMA has resumed the conduct." Wendler Decl. ¶ 6 (emphasis added). As Ambu's memorandum tacitly concedes, Mr. Wendler's "impression" is inadmissible hearsay. See Mem. 4 ("Ambu learned from its sales staff") (emphasis added). As a consequence, Ambu has no competent evidence to excuse its undue delay and has failed to make a prima facie case that it should be granted leave to add new counterclaims nine months into the case.

Moreover, even if Mr. Wendler had personal knowledge, his "impression" lacks any corroborating factual details and is inconsistent with the contemporaneous documentary evidence. While Ambu suggests that it did not bring its counterclaims earlier because it "was under the impression" that LMA had stopped engaging in the allegedly false marketing practices (Ambu Mem. 3), it offers no reason why it would or should have had that impression. To the contrary, Ambu should have had the *opposite* impression based on LMA's reaffirmation of the challenged sales practices in its response to Ambu's cease-and-desist letter. *See* Marzen Decl.,

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<sup>&</sup>lt;sup>3</sup> See also Chodos v. W. Publ. Co., 292 F.3d 992, 1003 (9th Cir. 2002)) (holding that district court's denial of a motion to amend did not constitute an abuse of discretion when the "new" facts were previously available to the moving party); Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg., No. C-92-3330 DLJ, 1995 WL 552168, at \*5 (N.D. Cal. Aug. 30, 1995) (denying leave to add counterclaim "that Hewlett-Packard has made false and damaging statements against its competitors," where "it appear[ed] that the alleged statements have been occurring over a lengthy time period, and there is no justification for the delay").

Ex. 6 (November 19, 2004 letter from LMA to Ambu reaffirming that LMA had "justifiable reason" for its representations about the Ambu product and in no way indicating that LMA would stop making them). While Ambu unilaterally and self-servedly wrote back that it considered the matter "closed," (Ex. 7) it had no basis to believe that LMA would or ever did cease the allegedly unfair business practices it seeks to challenge here.

In sum, Ambu presents no reason for its undue delay in seeking to assert its counterclaims against LMA. Even if Ambu did recently learn of "new facts" to support its claims, it clearly knew about its claims at the time it filed its answer (and indeed, for years before that). Because Ambu "could have pleaded [its counterclaims] in previous pleadings" (*Edwards Lifesciences*, at \*3), the factor of undue delay strongly supports denying Ambu's motion to amend.

## B. <u>Allowing Ambu to Assert Five New Unrelated Counterclaims Would Prejudice</u> LMA By Complicating and Delaying the Resolution of this Case

Allowing Ambu to add its five proposed counterclaims would clearly prejudice LMA. LMA filed this action more than nine months ago in October 2007, and has streamlined its case to a single patent to get quickly to the merits. A Scheduling Order, including discovery, expert, and trial deadlines, have been set based on the single patent claim in this case. Discovery, including documents production, has already begun. Allowing Ambu to add one federal and four state counterclaims based on LMA's sales and marketing practices would substantially prejudice LMA by requiring additional and extensive discovery and delay in the case. For example, many more depositions of customers and sales staffs of both parties would be required regarding the allegedly false statements and what effects they may have had, if any, on Ambu's customers and their purchasing decisions. See Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1139 (9th Cir. 1997) (setting forth the necessary elements of a Lanham Act false advertising claim).

Allowing Ambu to add its counterclaims would particularly prejudice LMA in light of the unrelated nature of Ambu's proposed false-advertising counterclaims. "It is well within a court's discretion to deny leave to amend where the proposed counterclaim presents a cause of action unrelated to the pending action." *Hewlett-Packard*, 1995 WL 552168, at \*5. "[W]here a

counterclaim does not arise from the same transaction or occurrence as the plaintiffs' claims and is therefore not particularly relevant, a court may properly conclude that such a claim should be asserted in an independent proceeding." *Tommy Hilfiger Licen., Inc. v. Bradlees, Inc.*, No. 99 CIV 4677(WK), 2001 WL 1702151, at \*6 (S.D.N.Y. Jan. 11, 2002); *see also Gucci America*, 2001 WL 21253, at \*6 n.7 ("Courts are more willing to deny leave to amend where the counterclaim is permissive, rather than compulsory, because defendants will not be barred from raising the claim in a different suit.") (citing Wright & Miller, 6 Fed. Prac. & Proc. 2d § 1430 (1990)).

Here, there is no relationship whatever between LMA's patent-infringement claim and Ambu's proposed false-advertising counterclaims. LMA's claim focuses solely on the narrow issue of whether *Ambu* has infringed LMA's patent. Ambu's counterclaims, on the other hand, focus on allegedly false representations made by *LMA*. The product features at issue in the patent case are totally separate from the features that give rise to Ambu's the allegations of unfair competition in the proposed counterclaims. The legal elements and evidence necessary to prove the two sets of claims do not overlap in any way. Indeed, Ambu does not even contend that its proposed counterclaims are compulsory or that it could not bring them in a separate action.

Given the unrelated, permissive nature of Ambu's counterclaims, Ambu's proposed amendment would plainly prejudice LMA by introducing a host of new issues into this litigation, complicating and altering its scope. Allowing Ambu's claims would require not only extensive additional document and witness discovery, but an array of responsive pleadings and motions that would greatly prolong this litigation and delay any recovery on LMA's infringement action. In addition, Ambu's claims – which include allegations of willful misconduct and a request for punitive damages – could confuse and prejudice the jury. Significantly, given the permissive nature of Ambu's claims, they can be raised without prejudice in a separate action.

Under these circumstances, Ambu's request to assert five new counterclaims should be denied. See Gucci America, 2001 WL 21253, at \*6 (denying leave to add new counterclaims that were "factually remote" from the plaintiff's claim and would result in "extensive" discovery and the prolongation of the litigation); Tommy Hilfiger, 2001 WL 1702151, at \*7 (denying leave

to amend where "the new counterclaims simply involve[d] different facts and issues than do Plaintiffs' claims," and would thus "require significant additional discovery and litigation, complicate the adjudication of Plaintiffs' claims, significantly delay the final disposition of this action, and quite likely result in jury confusion"); *Hewlett-Packard*, 1995 WL 552168, at \*3 (in denying leave to amend, court stressed that adding new counterclaim "would significantly broaden the issues, evidence, and discovery to be conducted").<sup>4</sup>

### C. Ambu Acted In Bad Faith By Failing to File the Claim Earlier

Although the factors of undue delay and prejudice are sufficient by themselves to deny Ambu's motion to assert five new counterclaims, the factor of bad faith further supports denial. As explained earlier, Ambu knew about LMA's marketing practices for many years and failed to challenge them, even when Ambu first answered in this lawsuit. Ambu's assertion of the claims now – nine months after the initiation of the litigation – suggests that its real reason for doing so is to complicate, confuse, and delay the case.

Ambu's bad faith is further reflected by its refusal to accept LMA's offer to extend the time for filing its responsive pleadings in this action pending the resolution of LMA's (ultimately successful) disqualification motion. Instead of accepting LMA's offer of an extension until after the disqualification issue was resolved, Ambu pressed ahead, filing its answer and two counterclaims alleging invalidity and non-infringement of LMA's patents on December 5, 2007. The only and (obvious) reason for Ambu to have acted so quickly when it did not have to was to support its argument that a change of counsel would unduly delay the case. Had Ambu asserted

<sup>&</sup>lt;sup>4</sup> Saes Getters, S.p.A. v. Aeronex, Inc., 219 F. Supp. 2d 1081 (S.D. Cal. 2002), on which Ambu relies (Mem. 4), is wholly distinguishable. In that case, the court granted a defendant in a patent-infringement action leave to assert a counterclaim alleging that plaintiff's patented product infringed a patent owned by the defendant. Id. at 1096. In so doing, however, the court emphasized that the two patents were for the same technology (id. at 1084) and that it was important to resolve issues relating to "dueling patents" in one action in order to "ensur[e] that the patents are interpreted in a consistent manner." Id at 1092, 1094. By contrast, there is no judicial efficiency to be achieved by trying Ambu's proposed false-advertising counterclaims with LMA's existing patent-infringement claim. Saes Getters is further distinguishable on the ground that at the time leave to amend was sought, discovery had been stayed by order of the magistrate judge as a result of lengthy settlement discussions. Id. at 1084, 1095. Here, written discovery has already been exchanged, document production has begun, and the parties are on the eve of commencing the claim construction process.

its five counterclaims challenging LMA's sales and marketing practices along with its answer (claims that would have led to extensive responsive motions), its delay argument would have been much weaker. Now that Ambu has been forced to change counsel (after requiring LMA to engage in costly and time-consuming litigation to obtain that result), Ambu should not be permitted to reverse field and assert a host of new and unrelated counterclaims against LMA.

### D. The Futility Factor Also Supports Denial of Leave to Amend

Lastly, the futility factor favors denial of Ambu's motion. The speciousness of Ambu's claims is demonstrated by the fact that Ambu itself failed to bring them until now, despite having known about the Ferson Study/LMA Brochure and LMA's marketing practices involving that Brochure for years. What is more, there is simply nothing false about LMA's marketing practices using that Brochure. Contrary to the allegation in Ambu's proposed counterclaims that the LMA Brochure "falsely claims" that Ambu's product "causes nerve damage" (¶ 15), the Brochure in fact states that the Ambu device presents a risk of nerve damage:

The Ambu™ Laryngeal Mask's high position is dictated by the pre-curved shape and the rigidity of its tube. This design helps insertion but may cause the cuff to press against the hyoid bone in some cases. There is a danger that the hypoglossal nerve, which governs motor functions of the tongue can be caught between the mask and the hyoid bone, leading to nerve palsy and problems with speech and swallowing. The failure to cover the esophagus also increases the risk of gastric insufflation, regurgitation and aspiration.

Marzen Decl., Ex. 4. Ambu's allegation that LMA accuses its product of "caus[ing] nerve damage" (Ambu Mem., Ex. A ¶ 15) is thus demonstrably false and the addition of counterclaims based on that allegation would thus be futile. To avoid the additional expense and burden on both the parties and the Court, LMA does not brief the numerous legal and factual deficiencies of Ambu's claims at this point, but will do so in full motions to dismiss and/or for summary judgment should that become necessary.

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**CERTIFICATE OF SERVICE** 

I hereby certify that on August 8, 2008, I caused the foregoing **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR LEAVE TO AMEND ANSWER AND COUNTERCLAIMS** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the applicable registered filing users.

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I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Dated: August 8, 2008

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